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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,206	06/21/2001	Sunao Hisada	400683	8134
23548	7590	12/28/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			GRUN, JAMES LESLIE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,206

Applicant(s)

HISADA ET AL.

Examiner

James L Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 18 October 2004 is acknowledged and has been entered. Claims 6, 7, and 9-21 have been cancelled. Claims 1-5 and 8 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The disclosure is objected to because of the following informalities: the specification is replete with grammatical and idiomatic errors too numerous to list specifically and should be carefully revised. Appropriate correction is required.

Claims 1-5 and 8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 8 are method claims and, as such, they should conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim. These claims are confusing because the preamble recites quantitatively detecting an antigen but the bodies of the claims do not recite a step relating detecting fluorescence to quantitatively detecting an antigen.

Applicant's arguments filed 18 October 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that one in the art would realize from the teachings of

the specification that quantitative detection can be performed by detecting fluorescence. This is not found persuasive because claims must be clear and complete and limitations from the specification are not read into the claims.

Claims 1-5 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Karger et al. (U.S. Pat. No. 5,348,633) in view of Fuchs et al. (U.S. Pat. No. 5,630,924) and Chen et al. (Electrophoresis 15: 13, 1994) for reasons of record.

Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger et al. in view of Fuchs et al. and Chen et al. as applied to claims 1-5 and 8 above, and further in view of Bodmer et al. (WO 89/01974) and Cabilly et al. (U.S. Pat. No. 4,816,567) for reasons of record.

Applicant's arguments filed 18 October 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the method of the invention allows separations of antigen and charge-modified antibody fragment when the isoelectric points of the unmodified antibody fragment and the antigen are the same or close to the same. This is not found persuasive because applicant is arguing a limitation not found in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Applicant urges that Karger et al., as modified, teach a complicated method of forming the labeled antibody fragments. This is not found persuasive for the reasons of record that the process of providing a given reagent does not serve to differentiate an identical reagent provided by another method and there is nothing on the record which provides evidence of a difference between the antibody fragments of the prior art provided by chemical modifications and those as

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instantly claimed provided recombinantly. Moreover the combination of Karger et al. in view of Fuchs et al. and Chen et al., and further in view of Bodmer et al. and Cabilly et al. teaches, for the reasons of record, recombinant production of the antibody fragments.

In response to Applicant's arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the reasons of record, ample motivations to combine the teachings of the references are provided.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant urges that Fuchs et al. do not teach the number of amino acids in the charge-modifying moiety and thus the reagents do

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not have a uniform isoelectric point. This is not found persuasive in view of the teachings of the reference regarding 3-500 charges (see e.g. col. 11) and the purification of charged antibody fragments by isoelectric focusing. Applicant urges that Chen et al. do not specifically exemplify charge-modified antibodies. This is not found persuasive because the disclosure of the reference is considered as a whole, not only for what is specifically exemplified. Applicant urges that Cabilly et al. teach different reasons for modifying antibodies. This is not found persuasive because the reference, as set forth, teaches the benefits of recombinant production of altered antibody molecules and fragments. In this case, for the reasons of record, ample motivations to combine the teachings of the references are provided.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James L. Grun, Ph.D.
December 23, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641
12/23/04